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November 12, 2023

VIA ECF

The Honorable Renée Marie Bumb, U.S.D.J.
Chief Judge, United States District Court
Mitchell H. Cohen Building & U.S. Courthouse
4th & Cooper Streets
Camden, NJ 08101

Re: *Corcept Therapeutics, Inc. v. Teva Pharm. USA, Inc.*, No. 18-3632 (consolidated)

Dear Chief Judge Bumb:

This firm, together with Quinn Emanuel, represents plaintiff Corcept Therapeutics, Inc. ("Corcept") in the above-captioned matter. We write in brief response to Teva's November 10, 2023 letter (D.I. 296).

Teva's submission accuses Corcept of engaging in an "untimely effort to present evidence of direct infringement that Corcept failed to adduce during the five-year pendency of this case." Teva's argument utterly ignores the context in which Corcept's request to reopen the trial record was made.

The direct infringement inquiry in Hatch-Waxman cases has never been focused on "the general prevalence of the induced activity." *Eli Lilly v. Teva Parenteral Medicines*, 845 F.3d 1357, 1368 (Fed. Cir. 2017). Accordingly, "patentees in Hatch-Waxman litigations asserting method patents do not have to prove that prior use of the NDA-approved drug satisfies the limitations of the asserted claims." *Vanda Pharms. v. W.-Ward Pharms.*, 887 F.3d 1117, 1130 (Fed. Cir. 2018). For the vast majority of the "five-year pendency of this case," Teva had not argued otherwise. Quite the opposite, as throughout the case Teva had argued there was a "high likelihood" that "clinicians might need to use combination therapy involving mifepristone and ketoconazole." *See* D.I. 277 at 2. Indeed, Teva did not raise a direct infringement defense based on doctors allegedly not co-administering mifepristone and strong CYP3A inhibitors in its opposition to Corcept's motion for summary judgment or its cross motion for summary judgment. *See* D.I. 202. Even after the *Genentech v. Sandoz*, 55 F.4th 1368 (Fed. Cir. 2022) opinion issued in December 2022, Teva did not supplement the pending summary judgment briefing. It was not until long after fact discovery had closed and the parties were preparing for trial that Teva began to contend otherwise to this Court, arguing in its September 2023 pretrial briefing based on *Genentech* that "Corcept has not set forth any evidence of past infringement." *See* D.I. 269 at 10. The Court recognized Teva's shift in position, noting: "To this Court's thinking, Teva seeks to have it both ways—'talks out of both sides'…." Tr. 108:9-14.

As Corcept explained in its opening post-trial brief, *Genentech* did not and could not change the *Eli Lilly* and *Vanda* infringement standard because it is a later-issued panel decision. D.I. 289 at § II.B (citing *Diamond Coating Techs. v. Hyundai Motor Am.*, 823 F.3d 615, 621 (Fed. Cir. 2016)). The evidence that Corcept adduced during discovery and presented at trial that doctors would practice the asserted claims when treating the relevant patient populations is sufficient to prove direct infringement under the *Eli Lilly* and *Vanda* standard. *Id.* at § II.A. This understanding of the relevant law is directly in line with the Court's instruction to the parties in denying their motions for summary judgment:

> Both Motions are hereby **DENIED**, **WITHOUT PREJUDICE**, until the Court hears expert testimony regarding the label's dosing regimens available when healthcare providers co-administer mifepristone with strong CYP3A inhibitors.

D.I. 229 at 1. The Court asked for expert testimony about the dosing regimens available ***when*** healthcare providers co-administer the drugs. And the evidence at trial clearly showed that for the three relevant patient populations, Teva's label requires doctors to practice the claimed inventions. D.I. 289 at § II.A. Corcept's presentation of evidence was reasonable based on (1) the *Vanda* and *Eli Lilly* infringement standards; (2) Teva's prior position that there was a "high likelihood" that "clinicians might need to use combination therapy involving mifepristone and ketoconazole"; (3) Teva's summary judgment papers that did not contest direct infringement; and (4) the Court's instructions to the parties in denying summary judgment.[1]

In its recent Letter Order (D.I. 292), however, the Court indicated it is of the opinion that evidence of past infringement is important to the direct infringement inquiry in this case.

> Because Corcept contends that physicians would infringe the claimed methods in the future by co-administering at an infringing sequence or dosage and by otherwise following Teva's label as instructed, [Pl.'s Br. 5–11], the existence—or absence—of such prior infringement evidence is important to this Court's analysis.

D.I. 292 at 2. While Corcept respectfully disagrees, it submitted a limited request that the Court reopen the trial record to consider such evidence if the Court finds the proffered declarations to be probative.

Teva does not disagree that it is within the Court's discretion to reopen the trial record for this very limited purpose. In fact, the Third Circuit affirmed a district court's decision to do just that in *Natural Resources Defense Council v. Texaco Refining & Marketing*. There, the trial court permitted two additional hours of testimony on a narrow issue, post-trial, where the

[1] And in any event, the evidence at trial also showed that (1) healthcare professionals desired to co-administer mifepristone with strong CYP3A inhibitors (D.I. 289 at 17); (2) healthcare professionals acted on that desire and did co-administer (*id.* at 8); and (3) the majority of patients were on the 900 and 1200 mg mifepristone monotherapy doses that would encompass the infringing patient populations (*id.* at 9-10).

"[f]ailure to adduce evidence adequate to sustain a judgment . . . [was] due to a reasonable misunderstanding among the parties and trial court." 2 F.3d 493, 504 (3d Cir. 1993). While Corcept has reasonable bases not to believe that evidence of past infringement is necessary here (as discussed *supra*), to the extent the Court is of that opinion, then there exists a reasonable misunderstanding of the appropriate legal standard to be applied. Third Circuit precedent clearly indicates that the Court can reopen the record to hear evidence relevant to that misunderstood issue.

Again, Teva does not dispute that the Court has discretion to re-open the record, but argues that the Court should not do so in view of the three-factor test applied in *In re Chemed Corp., Shareholder Derivative Litigation*, No. 13-1854, 2017 WL 1712530 at *5 (D. Del. Apr. 25, 2017). Teva does not dispute that in *Chemed*, the court held that the most compelling factor is whether the evidence sought to be introduced is especially important or probative, and Teva does not contest that factor is met. Teva instead argues that the record should not be reopened in this case because of the other two *Chemed* factors: "the timing of the motion and the moving party's explanation for failing to introduce the evidence earlier," and "whether reopening will cause undue prejudice to the nonmoving party." Corcept has explained why it did not introduce the evidence above sooner; and any prejudice to Teva can be cured by allowing Teva to depose the declarants and to submit limited supplemental briefing following those depositions.

Corcept would welcome a teleconference with Your Honor to further discuss these issues. Thank you for Your Honor's kind attention to this matter.

Respectfully yours,

William C. Baton

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cc: All counsel of record (via e-mail)